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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,448	04/16/2004	Greg Collier	007193-4	4190

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EXAMINER	
STANDLEY, STEVEN H	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,448	COLLIER ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5-18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, SEQ ID NO: 1 in the reply filed on 12/15/06 is acknowledged. The traversal is on the ground(s) that the products are structurally and functionally similar. Applicant cites page 19 as teaching similarity of sequences. However, the passage cited merely describes what is meant by similarity. The sequences themselves do not share substantial structural and functional features as near as can be ascertained by the examiner. Applicant also argues that the MPEP allows for up to 10 independent sequences to be examined. This is not found persuasive because this policy was officially rescinded as of February 2007. See the following link: http://patentdocs.typepad.com/patent_docs/2007/03/uspto_news_offi.html. Sequences are to be considered for independence, relatedness, distinction and burden as for claims to any other type of molecule. Thus, because the sequences are not structurally or functionally related, it would be a burden to search more than one sequence.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Priority to the PCT AU02/01405 filed 10/16/02 is acknowledged.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 3/27/06 has been considered by the examiner in part by the examiner. However, several prior art references consist merely of database sequences denoted by Accession numbers from

genbank and EMBL. The examiner has considered them insofar as possible. However, He cannot determine the relevance of these sequences to the instant claims without appropriate comparisons, such as sequence alignments.

Claim Objections

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-4 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The nucleic acid (SEQ ID NO: 1) claimed is disclosed as useful as either a therapeutic agent or a diagnostic agent for the treatment of obesity and related diseases such as diabetes. However, the data presented in the specification are limited to rt-pcr results presented in Figure 1, which are meant to demonstrate that the instant nucleic acid is elevated in the gut after feeding in the Israeli desert rat. Firstly, the error bars, which are reasonably larger than the mean bar, do not in any way suggest that this is a significant or reliable result compared with the fasted group or the refed group. Secondly, even if it were significant, this limited disclosure does not indicate the nucleic acid sequence would be useful in either diagnosing or treating obesity or related

diseases. While it might be elevated after feeding repeatedly (the examiner asserts that from the disclosure it cannot be determined whether it is elevated more often than not after feeding), at most, this data suggests the sole value of SEQ ID NO: 1 as a marker would be related to marking whether or not the animal has fed repeatedly (which is not disclosed in the specification as a utility). This is in no way diagnostic of obesity, as normal non-obese animals also feed repeatedly.

The specification presents no data that would indicate any utility as a therapeutic for obesity, diabetes, anorexia, or any other eating-related diseases. Further, the specification discloses that the nucleic acid encodes a protein with little homology to any other known protein in the database. Therefore no information can be derived as to the function of the protein encoded by the instant nucleic acid by such a comparison. The specification also does not characterize the nucleic acid or the encoded protein in any way such that the function of the protein can be surmised by one skilled in the art.

The art positively indicates that obesity and related pathologies represent a complex disease state that cannot be explained by analyses of one gene. Permana et al say as much: "Despite the remarkable advances in the understanding of the molecular biology that may explain the etiology of obesity and its pathophysiologic consequences, the exact cause of weight gain in the majority of people remains unknown, and the precise links between obesity and insulin resistance have yet to be unequivocally

Identified. This is very likely due to the fact that common, metabolically complex diseases, such as obesity and insulin resistance, are not characterized by a simple genetic architecture in which a single gene is necessary and sufficient to cause the

disease. Rather, they are caused by multiple susceptibility alleles, which is consistent with the close to ***100 quantitative trait loci*** with linkage to obesity or insulin resistance uncovered to date in human genome-wide scans. Individuals who carry only one or some of these alleles may still not develop the disease because they lack another allele (gene– gene interaction) or are not exposed to the precipitating environment [emphasis added, page 134, left col." Moreover, the results disclosed in the specification do not even indicate a relationship of the gene of SEQ ID NO: 1 with obesity, or any eating disorder or pathology related to it.

5. Claims 1-4 and 19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-4 and 19 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of

claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is complex because it is a method of diagnosis or treatment of obesity which is a complex disease with a multitude of factors and independent pathways that may (or may not) contribute to its development.

The state of the art is that there are very few treatments of obesity with limited effects. For instance, Hofbauer et al assert that "the history of drug treatment of obesity is no success story [p 475,. Left col]." Furthermore, linkage analysis indicates genetic factors contributing to obesity are on the order of 100 different quantitative trait loci (Permana et al, 2004). Thus, the prior art indicates that both genetic diagnosis and pharmacological treatment of obesity is unpredictable.

The specification fails to support the use of the nucleic acid of SEQ ID NO: 1 for either the diagnosis or treatment of obesity, nor of any related condition. The specification presents no data that would indicate any utility as a therapeutic for obesity, diabetes, anorexia, or any other eating-related diseases. Further, the specification discloses that the nucleic acid encodes a protein with little homology to any other known protein in the database. Therefore no information can be derived as to the function of the protein encoded by the instant nucleic acid by such a comparison. The specification also does not characterize the nucleic acid or the encoded protein in any way such that the function of the protein can be surmised by one skilled in the art.

Due to the large quantity of experimentation necessary to make and use the invention, the lack of direction/guidance presented in the specification regarding such, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which established the unpredictability of the art, and the breadth of the claims which fail to recite functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

6. Claims 1-4 and 29 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn nucleic acids having at least 30% sequence identity with a particular named nucleic acid, or to claims that can reasonably be interpreted as claiming any fragment the nucleic acid of SEQ ID NO: 1. Unknown and undisclosed nucleic acids with homology to SEQ ID NO: 1 would number on the order of 4^{126} or $7.23x10^{75}$. The claims do not require that the nucleic acid to encode a protein that possesses any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Therefore, there are no clear structural limitations on the complex of nucleic acids claimed. Thus, the claims are drawn to a genus of nucleic acids that have no structural or functional limitations.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. In the instant application, no such distinctions have been disclosed. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only nucleic acid comprising ***the*** nucleic acid sequence set forth in a SEQ ID NO:1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by accession number AL077475 (June, 1999; see appendix A).

The sequence of AL077475 discloses "**a** nucleic acid having at least 30% identity to **a** nucleic acid sequence of SEQ ID NO: 1 (see best local similarity, 53.5%). The claim as written does not preclude fragments of SEQ ID NO: 1, which have at least 30% identity. Thus the prior art meets the limitations of claim 1. Further, the prior art sequence discloses "a nucleotide sequence..." of claim 2 and of claim 19.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
3/13/07